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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/634,369	08/09/2000	James K. Liao	18989-004 (BWH-4)	5676

7590 03/13/2002

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EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/634,369	LIAO ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *1-9,20,22-24 and 29-32* is/are withdrawn from consideration.

5)☒ Claim(s) *28* is/are allowed.

6)☒ Claim(s) *10-19,21 and 25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The following is responsive to the election received Jan. 11, 2002.

Applicant's election of Group II claims 10-19, 21, 25-28 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

Applicant's Information Disclosure Statement received Aug. 7, 2001 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Allowable Subject Matter

Claim 28 is free from the prior art because the prior art does not disclose or fairly suggest Applicant's claimed method.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 26, 27 are rejected under 35 U.S.C. 102(a) as being anticipated by Node et al.

Node et al. disclose a method inhibiting VCAM-1 expression by contacting endothelial cells with physiological concentrations of [11,12]-EET. Please refer to the abstract submitted herewith.

Node et al. also disclose a method of inhibiting IKK activity in a cell, the method comprising treating cells with [11,12]-EET. The results demonstrated that [11,12]-EET inhibited TNF-alpha induced IKK activity therefore "modulating" NK-κB activity. Please see the abstract.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 10-19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Node et al. in view of Zeldin et al.

Node et al. as applied above. Moreover, Node et al. disclose that [11,12]-EET has anti-inflammatory actions and may play a role in vascular inflammation and atherogenesis.

Node et al. do not disclose producing [11,12]-EEt from the claimed cytochrome P450 epoxygenases/enzymes nor do Node et al. teach treating inflammation in a subject, i.e. in vivo; however, the Examiner turns to Zeldin et al. which discloses that cytochrome P450 monooxygenases such as CYP2B, CYP1A, CYP2E, CYP2J , CYP2J2, CYP2J3 form epoxyeicosatrienoic acids. Please see the abstract; page 1111 first and second column; page 1112, first column, the paragraph beginning with "Researchers....."

It would have been obvious to modify the methods of Node et al. to use EET's produced from the claimed cytochrome P450 epoxygenase/enzymes because Zeldin et al. disclose that EET's are products of P450 epoxygenases such as CYP2J, CYP2B, etc. and one of ordinary skill in the art would reasonably expect [11,12]-EET produced from these P450 epoxygenases to have anti-inflammatory actions and thus be equally effective in treating inflammatory conditions.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of Node et al. to include in vivo administration because one of ordinary skill in the art, based on the desirable anti-inflammatory actions disclosed by Node et al., would reasonably expect [11,12]-EET to treat or even prevent inflammation in a subject. Such a modification would have been motivated by the reasoned expectation of successfully treating inflammation in a subject.

With respect to the claimed causes of the inflammation, based on the anti-inflammatory actions disclosed by Node et al., one of ordinary skill in the art would reasonably expect [11,12]-EET to treat inflammatory conditions resulting from the claimed disorders.

6. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Node et al. in view of Zeldin et al. as applied to claims 10-19, 25 above, and further in view of D'Amato 5,593,990 or Hammock et al., 5,955,496.

Node et al. and Zeldin et al. as applied above.

Node et al. and Zeldin et al. do not disclose additionally administering an epoxide hydrolase inhibitor to the subject; however, the Examiner refers to (1) D'Amato which discloses a method for treating chronic inflammation in a human or animal comprising administering a composition containing an epoxide hydrolase inhibitor (col. 11, lines 43-64); or (2) Hammock et al., which discloses a method for treating inflammatory diseases comprising administering an effective amount of an epoxide hydrolase inhibitor. Please see col. 2, lines 63-67; col. 5, lines 56-67.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of Node and Zeldin to administer an epoxide hydrolase inhibitor along with [11,12]-EET, which also has anti-inflammatory activity, because one of ordinary skill in the art would reasonably expect the combined effect of these two agents to be effective in treating inflammatory conditions. In other words, such a modification to combine would have been motivated by the reasoned expectation that the additive effect of the combination of [11,12]-EET and epoxide hydrolase inhibitor would be successful in treating a subject suffering from inflammatory conditions.

Conclusion

Claims 10-19, 21, 25-27 are rejected.

Claim 28 is free from the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

March 11, 2001

Cybille Delacroix-Muirheid
Patent Examiner Group 1600